The effect of internal thoracic artery grafts on long-term clinical outcomes after coronary bypass surgery

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Objectives: We sought to compare long-term outcomes after coronary bypass surgery with and without an internal thoracic artery graft.

Methods: We analyzed clinical outcomes over a median follow-up of 6.7 years among 3,087 patients who received coronary bypass surgery as participants in one of 8 clinical trials comparing surgical intervention with angioplasty. We used 2 statistical methods (covariate adjustment and propensity score matching) to adjust for the nonrandomized selection of internal thoracic artery grafts.

Results: Internal thoracic artery grafting was associated with lower mortality, with hazard ratios of 0.77 (confidence interval, 0.62–0.97; $P = .02$) for covariate adjustment and 0.77 (confidence interval, 0.57–1.05; $P = .10$) for propensity score matching. The composite end point of death or myocardial infarction was reduced to a similar extent, with hazard ratios of 0.83 (confidence interval, 0.69–1.00; $P = .05$) for covariate adjustment to 0.78 (confidence interval, 0.61–1.00; $P = .05$) for propensity score matching. There was a trend toward less angina at 1 year, with odds ratios of 0.81 (confidence interval, 0.61–1.09; $P = .16$) in the covariate-adjusted model and 0.81 (confidence interval, 0.55–1.19; $P = .28$) in the propensity score–adjusted model.

Conclusions: Use of an internal thoracic artery graft during coronary bypass surgery seems to improve long-term clinical outcomes. (J Thorac Cardiovasc Surg 2011;142:829-35)

The internal thoracic artery (ITA) has better long-term patency than the saphenous vein when used as a conduit in coronary artery bypass graft surgery (CABG).[1-3] Although it is widely believed that this higher patency rate leads to better long-term clinical outcomes, there are few data to support this assumption. Only one small randomized trial has compared use of ITA grafts with use of saphenous vein grafts.[4] In that trial patients assigned to receive an ITA graft had fewer composite end points of cardiac death, myocardial infarction, repeat revascularization, and cardiac hospitalization over 10 years (12/39 vs 21/41, $P < .05$) but did not differ significantly in any other end point. The results of this trial are not definitive because of its small size and because the outcome differences were driven mostly by cardiac hospitalizations rather than death or myocardial infarction. Observational nonrandomized studies of between 743 and 5,931 patients who underwent CABG in the 1970s suggest that patients who received an ITA graft had improved long-term survival compared with that of patients who received only saphenous vein grafts.[5-7] Patients selected to receive an ITA graft, however, differed in many clinical characteristics from patients selected to receive only vein grafts, and these differences might have introduced selection bias into the comparison of outcomes that can be difficult to control by using statistical methods. Newer approaches to the analysis of observational data might help control for differences between patients selected for different treatments,[8-11] although selection biases not

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Abbreviations and Acronyms
CABG = coronary artery bypass graft surgery
MI = myocardial infarction

captured by measured covariates might still exist.[12] The purpose of this study was to apply both propensity score methods and covariate adjustment methods to compare the long-term outcomes of a more contemporary sample of patients who underwent CABG with or without an ITA graft.

MATERIALS AND METHODS

Investigators from 10 randomized trials of CABG versus percutaneous coronary intervention for multivessel coronary disease pooled individual patient data as part of a collaborative analysis of long-term treatment outcomes, as described previously.[13] The present study is based on data from the 8 trials that provided individual patient data on the use of ITA grafts among patients assigned to CABG.[13] Use of ITA grafting in these trials was based on the surgeon's preference and was not randomized.

We used multivariable logistic regression to compare baseline clinical characteristics of patients who received an ITA graft with those who did not. The results of this model were used to create a propensity score that estimated the probability of each patient receiving an ITA graft. For the propensity score–matched analyses, we identified pairs of patients, one of whom received an ITA graft and one of whom did not, using an algorithm[14] that first paired the patients with the closest propensity scores, then paired the patients with the next closest propensity scores, and so on, and stopped matching when propensity scores differed by more than 0.01. We required that each pair of patients be drawn from the same clinical trial and be matched on the presence or absence of diabetes.

We assessed time to event for 3 major clinical outcomes: death, death or myocardial infarction, and death or myocardial infarction or repeat revascularization. These end points were defined by each trial using specific protocol definitions.

We used Cox proportional hazards models to analyze time-to-event outcomes, and logistic regression to analyze angina at 1 year. We performed 2 sets of analyses for each outcome. In the first set of analyses, we compared outcomes of patients with and without an ITA graft among all patients, adjusting for the patients' baseline clinical characteristics (Table 1) and stratifying by trial. In the second set of analyses, we compared outcomes of patients with and without an ITA graft in the subset of patients who were matched on propensity score, adjusting for baseline clinical characteristics and stratifying by trial. All statistical analyses were performed with R Version 2.8.1 software.

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RESULTS

Data on ITA use were available for 3,087 patients who received CABG in one of 8 clinical trials. The 2,573 (83%) patients who received an ITA graft were significantly less likely to be female or have heart failure or a prior myocardial infarction and significantly more likely to have proximal disease of the left anterior descending coronary artery or triple-

TABLE 1. Baseline characteristics by use of ITA

	All patients			Matched patients		
	No ITA (n = 514)	ITA (n = 2,573)	*P* value	No ITA (n = 437)	ITA (n = 437)	*P* value
Age, y (mean)	61.0	60.3	.15	60.7	60.6	.74
Female sex	30%	22%	.0002	28%	28%	.84
Diabetes	17%	16%	.82	13%	13%	1.00
Hypertension	45%	46%	.62	44%	47%	.35
Hyperlipidemia	52%	53%	.52	51%	52%	.61
Current smoker	22%	25%	.18	23%	19%	.11
Proximal LAD	35%	52%	<.0001	35%	34%	.64
3-Vessel disease	29%	39%	<.0001	29%	27%	.49
Unstable angina	49%	46%	.14	53%	52%	.90
Previous MI	50%	45%	.04	49%	48%	.70
Heart failure	7%	3%	.0005	5%	4%	.22
Abnormal LV function	18%	17%	.62	19%	19%	.80
Peripheral vascular disease	13%	11%	.13	13%	13%	.89
Study						
ARTS	40	539		40	40	
BARI	163	729		152	152	
ERACI-II	9	198		9	9	
GABI	96	62		54	54	
MASS II	10	188		10	10	
RITA	126	364		116	116	
SoS	36	451		35	35	
Toulouse	34	42		21	21	

ITA, Internal thoracic artery; *LAD*, left anterior descending coronary artery; *MI*, myocardial infarction; *LV*, Left ventricular; *ARTS*, Arterial Revascularization Therapies Study; *BARI*, Bypass Angioplasty Revascularization Investigation; *ERACI-II*, Argentine Randomized Study: Coronary Angioplasty with Stenting Versus Coronary Bypass Surgery in Multivessel Disease; *GABI*, German Angioplasty Bypass Surgery Investigation; *MASS-II*, Second Medicine, Angioplasty or Surgery Study; *RITA*, Randomized Intervention Treatment of Angina; *SoS*, Stent or Surgery.

TABLE 2. Propensity score for receiving an ITA graft

	Coefficient	*P* value
Age, y (mean)	–0.013	0
Female sex	–0.485	.0001
Diabetes	–0.072	.63
Hypertension	–0.092	.42
Hyperlipidemia	0.014	.92
Current smoker	–0.049	.72
Proximal LAD	0.697	<.0001
3-Vessel disease	0.298	.014
Unstable angina	–0.024	.87
Previous MI	–0.172	.12
Heart failure	–0.973	<.0001
Abnormal LV function	–0.006	.97
Peripheral vascular disease	0.013	.95
Study		
ARTS	Reference	
BARI	–0.883	<.0001
ERACI-II	0.458	.24
GABI	–3.055	<.0001
MASS-II	–0.082	.82
RITA	–1.661	<.0001
SoS	0.056	.82
Toulouse	–2.260	<.0001
Intercept	3.266	<.0001

ITA, Internal thoracic artery; *LAD*, left anterior descending coronary artery; *MI*, myocardial infarction; *LV*, left ventricular; *ARTS*, Arterial Revascularization Therapies Study; *BARI*, Bypass Angioplasty Revascularization Investigation; *ERACI-II*, Argentine Randomized Study: Coronary Angioplasty with Stenting Versus Coronary Bypass Surgery in Multivessel Disease; *GABI*, German Angioplasty Bypass Surgery Investigation; *MASS-II*, Second Medicine, Angioplasty or Surgery Study; *RITA*, Randomized Intervention Treatment of Angina; *SoS*, Stent or Surgery.

vessel disease (Table 1). The use of ITA grafts also varied significantly by trial, ranging from 39% to 96%. The multivariable propensity score showed that the strongest predictor of whether a patient received an ITA graft was the trial in which the patient was enrolled, followed by heart failure, presence of disease in the proximal left anterior descending coronary artery, female sex, and the presence of 3-vessel disease (Table 2). We were able to match on propensity score 437 (85%) of the 514 patients who did not receive an ITA graft with 437 patients from the same trial who did receive an ITA graft. As expected, the matched groups had very similar baseline characteristics (Table 1).

Among all patients receiving CABG, the median follow-up of surviving patients was 6.7 years (interquartile range, 5.1–10.0 years), with a mean follow-up of 7.8 years and a maximum follow-up of 16.3 years. The unadjusted Kaplan–Meier mortality rate at 5 years was 2.6% lower among patients who received an ITA graft than among patients who received vein grafts only, and at 10 years, the mortality rate was 1.9% lower in the ITA group (Table 3). In a Cox model that was stratified by study and adjusted for all of the baseline characteristics in Table 1, use of an ITA graft was associated with a significantly lower risk of death, with a hazard ratio of 0.77 (confidence interval, 0.62–0.97; $P = .02$). Use of an ITA graft was also associated with a significantly reduced chance of the composite end point of death or myocardial infarction and the composite end point of death or myocardial infarction or repeat revascularization (Tables 3 and 4). Angina at 1 year was also less frequent among patients who received an ITA graft, although not significantly so (Tables 3 and 4).

Among 437 pairs of patients matched on propensity score, study, and diabetes, 5-year mortality was 2.3% lower among patients who received an ITA graft than among patients who did not, and at 10 years, mortality was 2.5% lower in the ITA group (Figure 1 and Table 3). In a Cox model stratified by study, use of an ITA graft was associated with a lower risk of death, with a hazard ratio of 0.78 (confidence limits, 0.57–1.05; $P = .10$). The hazard ratio was essentially unchanged after additional adjustment for baseline characteristics (0.77; confidence limits, 0.57–1.05; $P = .10$). There was a significantly lower incidence of the composite end point of death or myocardial infarction (MI; Figure 2 and Table 3) and of the composite end point of death, MI, or repeat revascularization (Figure 3 and Table 3). Angina at 1 year was less frequent among patients who

TABLE 3. Incidence of clinical outcomes in follow-up by use of the ITA based on pooled unadjusted data

	All patients			Matched patients		
Outcome	No ITA (n = 514)	ITA (n = 2,573)	Unadjusted *P* value	No ITA (n = 437)	ITA (n = 437)	Unadjusted *P* value
Death (%)						
5 y	10.4	7.8	.04	10.4	8.1	.12
10 y*	22.5	20.6	.17	21.7	19.2	.18
Death or MI (%)						
5 y*	19.2	15.4	.02	19.1	13.8	.02
10 y*	33.3	30.4	.10	32.2	27.6	.07
Death, MI, or repeat revascularization (%)†						
5 y*	20.1	14.3	.002	19.8	16.9	.14
10 y*	40.8	37.4	.08	40.2	36.6	.14
Angina at 1 y (%)	17.8	12.8	.004	17.8	15.4	.17

ITA, Internal thoracic artery; *MI*, myocardial infarction. *Kaplan–Meier estimates. †Data omit the Toulouse study.

TABLE 4. Comparative outcomes: Hazard ratio for ITA versus no ITA in Cox models stratified by study and adjusted for baseline clinical characteristics

	All patients (n = 3,087)		Matched patients (n = 874)	
	Hazard ratio (CI)	*P* value	Hazard ratio (CI)	*P* value
Death	0.77 (0.62-0.97)	.02	0.77 (0.57-1.05)	.10
Death/MI	0.83 (0.69-1.00)	.05	0.78 (0.61-1.00)	.05
Death/MI/repeat procedure	0.82 (0.69-0.98)	.03	0.85 (0.67-1.08)	.18
Angina* (1 y)	0.81 (0.61-1.09)	.16	0.81 (0.55-1.19)	.28

The data shown are odds ratios (95% confidence intervals). *ITA*, Internal thoracic artery; *CI*, confidence interval; *MI*, myocardial infarction. *Logistic regression model used to assess angina at 1 year.

received an ITA graft, although not significantly so (Tables 3 and 4).

DISCUSSION

Our analysis confirms that patients who receive ITA grafts differ significantly from patients who receive only vein grafts in a number of prognostically important clinical characteristics (Table 1), including sex, a history of MI and heart failure, and the extent of coronary artery disease (Table 2). After adjusting for these and other differences by using several different statistical methods, we found that use of an ITA graft was associated with a 23% lower relative risk of death over a 6.7-year median follow-up (Table 4). These results are generally consistent with the 38% risk reduction over 10 years reported by Loop and associates,[5] the 27% risk reduction over 15 years reported by Cameron and coworkers,[6] and the 32% risk reduction over 20 years reported by Cameron and colleagues.[7] The long-term risk reductions associated with use of ITA grafts are not as striking as the 56% to 74% reductions in procedural mortality reported by large clinical databases,[15-18] but comparisons of 30-day mortality after CABG might be more susceptible to selection bias.

In addition to an association with lower mortality, ITA use in our study was also associated with lower rates of myocardial infarction, repeat revascularization, and angina (Tables 3 and 4). The consistency of the effect of ITA use on these additional end points is reassuring. Our results, in

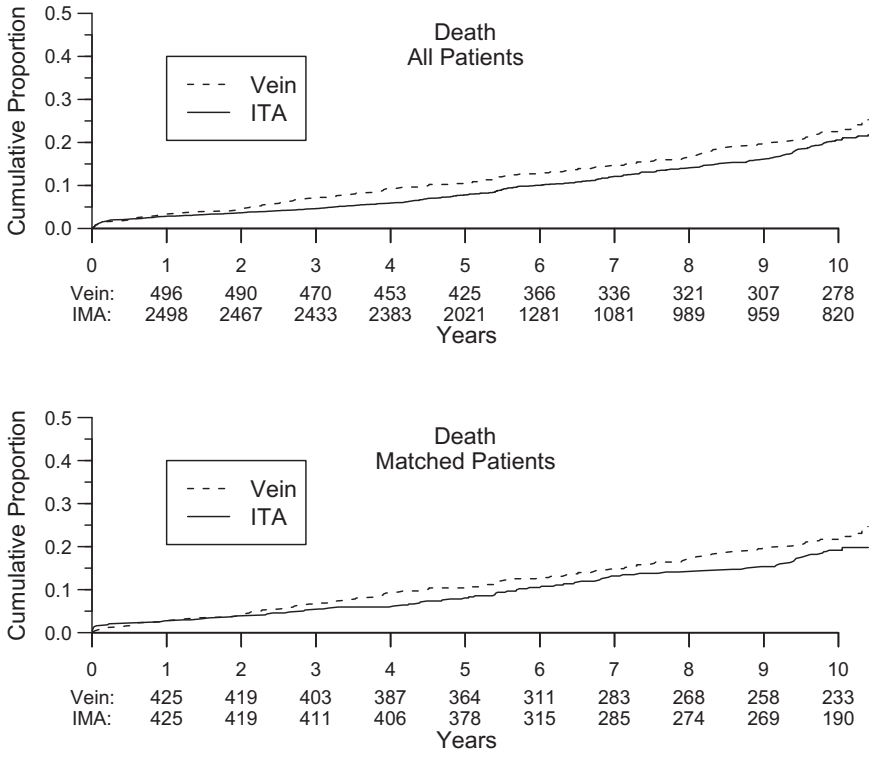

FIGURE 1. Cumulative rate of mortality *(vertical axis)* over 10 years of follow-up *(horizontal axis)* in patients matched on propensity score. The outcome of patients who received an internal thoracic artery *(ITA)* graft is indicated by the *solid line*, and the survival of patients who received only vein grafts is indicated by the *dashed line*. The number of patients followed alive at each annual interval in each group is indicated below the horizontal axis.

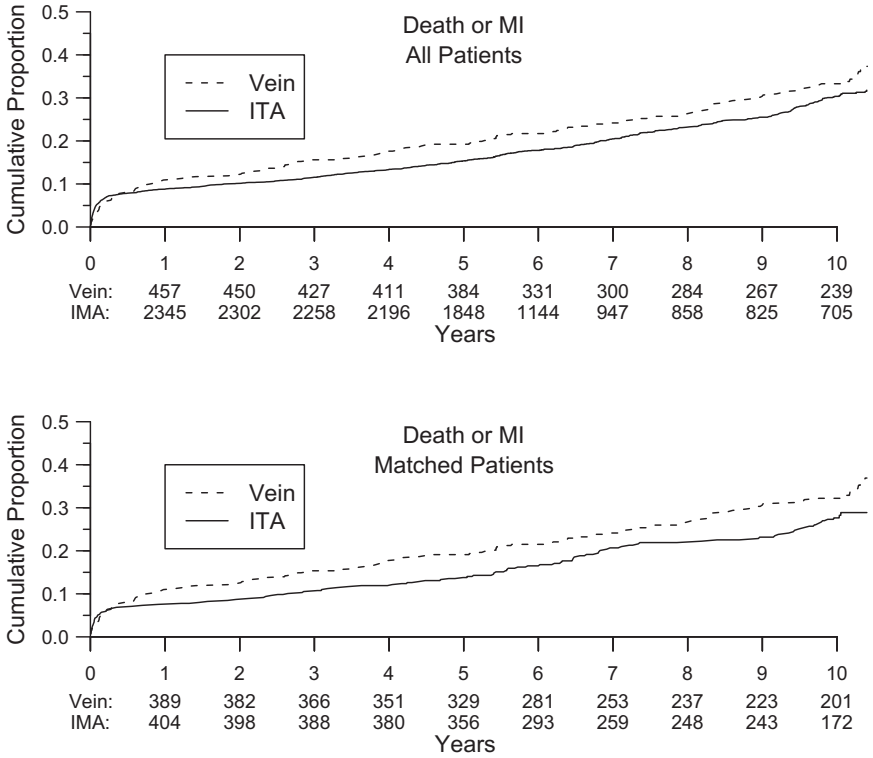

FIGURE 2. Cumulative rate of death or myocardial infarction *(MI)* over 10 years of follow-up. Format is as in Figure 1.

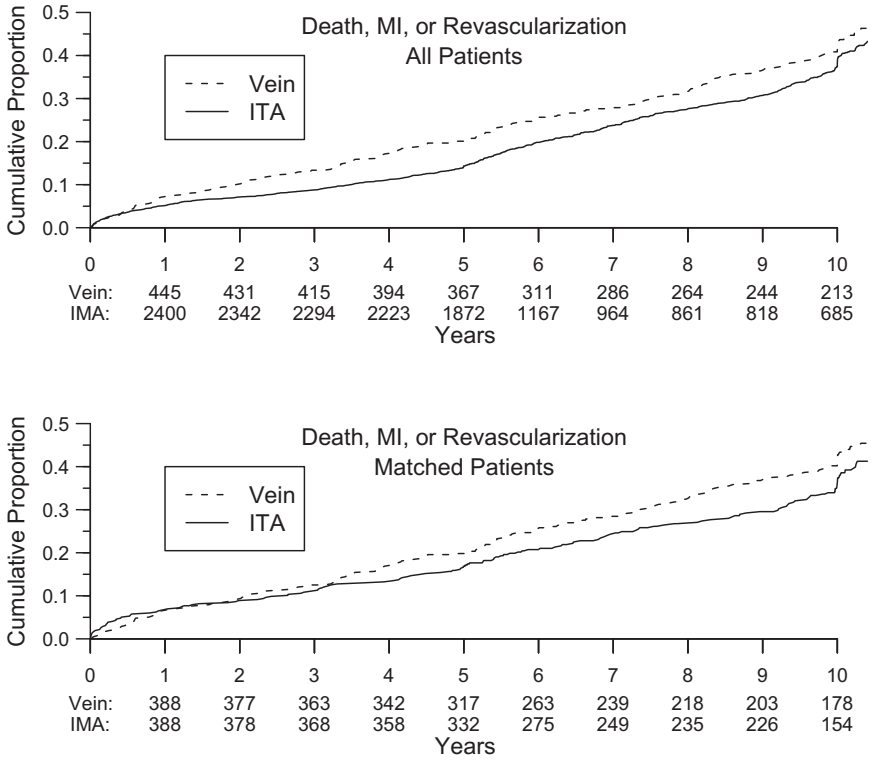

FIGURE 3. Cumulative rate of death, myocardial infarction *(MI)*, or repeat revascularization over 10 years of follow-up. Long-term data on repeat procedures were not available from the Toulouse study. Format is as in Figure 1.

conjunction with those of earlier studies,[5,6] suggest that the better long-term patency of ITA grafts seems to translate into improved long-term clinical outcomes.

ITA grafting has not been tested in a large, long-term clinical trial, and therefore nonrandomized observational comparisons are the only source of information on the comparative effectiveness of ITA and vein grafts. Patients selected for alternative treatments differ in a number of ways, however, and therefore multivariable statistical methods have been used in an attempt to adjust for clinically important differences between patient groups. A variety of methods has been used,[19] including direct adjustment for confounding factors in a multivariable model, propensity score adjustment and matching,[8,9] and instrumental variables methods,[20,21] among others. Typically, investigators choose just one of these methods to analyze their data, but recent studies have shown that the results of alternative models applied to the same dataset might well differ.[22,23] We applied several approaches to the analysis of these data to evaluate whether the results would be affected by the choice of a statistical model. The magnitude of the effect of the ITA on several outcome measures was quite similar whether we used direct adjustment for baseline covariates or propensity score matching, although the confidence limits were wider when the sample size was reduced by matching. These alternative approaches might have yielded similar hazard ratios in the present study because some adverse prognostic factors had a higher prevalence in the ITA group (3-vessel disease and proximal left anterior descending disease), whereas other adverse prognostic factors had a lower prevalence in the ITA group (abnormal left ventricular function and prior myocardial infarction). Consequently, prognosis at study entry might have been relatively similar in the ITA and vein graft groups because of offsetting imbalances in different baseline characteristics. Furthermore, all patients in this analysis had been selected to participate in a clinical trial, which might have led to a narrower range of clinical characteristics than seen in unselected patients undergoing CABG. The similarity in the results of alternative statistical approaches in our study should not be interpreted because showing these methods would yield equivalent results in other observational treatment comparisons.

This study has a number of limitations. Although the data were drawn from clinical trials of CABG and coronary angioplasty, the use of ITA grafting was not randomized and varied considerably among the participating trials and according to patients' characteristics. We had only relatively simple clinical data available on all patients and therefore were unable to adjust for characteristics, such as the extent of atherosclerosis, and residual selection bias due to unmeasured confounders might be present.[12] The length of follow-up in this study (median, 6.7 years) might not have been long enough to show the full clinical effects of ITA grafting in light of the accelerated rate of vein graft failure after 7 years. Finally, all patients underwent CABG between 1988 and 2000 and might not completely reflect the results of contemporary CABG, although all were treated in centers with excellent cardiac surgical programs.

In conclusion, these data provide additional evidence that use of an ITA graft appears to improve long-term outcomes after CABG and suggest that ITA use might be a reasonable process measure of the quality of care for CABG.[24,25]

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